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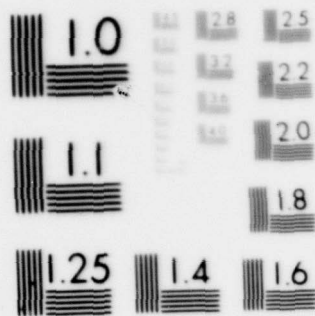
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PROJECT MILES: BIOMEDICAL RESEARCH
AND COORDINATION IN SAFE FIELD EXERCISES,

JUN 1978

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The Multiple Integrated Laser Engagement System (MILES) is the core system for a family of laser engagement simulators which have the potential to revolutionize Army tactical unit training.

MILES devices are being developed for the M16 rifle, the Army's full family of machineguns, the VIPER, DRAGON, TOW, the main battle tanks (M60A1, A2, A3), and the M551 AR/AAV. Follow-on efforts will expand the MILES system into air defense weapons, helicopters, artillery, high performance aircraft, and enemy weapons systems. The prototype packages consisted of laser transmitters which simulated the effect of the weapons, the laser detector array which detects and decodes incoming laser signals, and hit indicating mechanisms which combine audio and visual signals to convey near misses and kills.

The system uses low power gallium-arsenide (GaAs) lasers. Each device is lightweight, and its addition to the base weapon will not affect the normal handling, accuracy, or performance of that weapon. For every weapons system involved, the laser transmitter will have a hit probability comparable to the weapon simulated, as

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well as duplicating the weapons' effects. An infantryman, for example, can "kill" another infantryman with his M16 device equipped rifle, but cannot disable a tank. Conversely, a tank can "kill" not only another tank, but also TOW crews and infantrymen. The key to this is distinct pulse codes for each weapon and discrimination logic in each detector.

By duplicating the ranges and simulating the lethality effects and characteristics of direct fire weapons, realistic, two-sided exercises can be conducted with reduced controller requirements and increased training value.

The MILES program will not only provide greater fidelity, it will extend tactical engagement simulation to full company team and battalion task force level training to include night operations. The MILES basis of issue for each active Army division will include enough devices to permit two battalion task force exercises to be conducted simultaneously. Operational testing of the MILES system is scheduled for August 1973 with production and initial issue beginning in 1979.

Proper operation of this system requires the laser to be purposely directed at personnel. Ocular exposure approaches certainty. Field deployment will therefore ultimately reflect the confidence of the user in his understanding of the ocular hazard of the injection diode laser. Cognizance of this fact led to a meeting in Orlando, FL, on 4 February 1976 with personnel from the US Army Environmental Hygiene Agency; the Project Manager for Training Devices, Orlando, FL, and the contractor, to discuss the planned engineering development model of the MILES laser system (1).

The meeting attendees concluded the proposed MILES system emitted optical radiation exceeding current protection standards (Class 1-System). In response to the recommendation that further biological research be performed, those groups involved in project MILES convened at the Letterman Army Institute of Research (LAIR) in April 1976 for a review of the biomedical effects of gallium-arsenide laser radiation. It was pointed out that it is not sufficient to simply test the MILES device against a biological system (the eye) in controlled laboratory situations. The assignment of this system to a "safe" category (Class 1) is controlled by existing regulation AR 40-46 (2) and TB MED 279 (3). A research program bearing on the provisions of these regulations was outlined.

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The fundamental requirement was to produce data that would indicate a need to modify existing standards, which is based in part, on limited data. Experiments were designed to answer questions and provide data on the damage threshold for a single-pulse exposure at the GaAs wavelength (905 nm) and the effect of exposure to pulse trains at the MILES code and frequency. In addition, experiments were designed to study the effect of the non-circular irradiation geometry resulting from exposure to collimated GaAs radiation (4). The most direct method to provide these data would be through the direct evaluation of retinal lesions created by exposure to a pulsed GaAs system. However, the injection diode laser was an uncooperative source when one attempted to optically couple the emission onto the retina, to the point where no retinal lesion had been successfully produced with a laser operating under the variables required of Project MILES. These variables approach the limits of a single-junction, pulsed, room temperature, GaAs laser.

The ocular hazard at a wavelength of 860nm had previously been determined for 120 KHz Pulse Repetition Frequency (PRF) radiation from a cryogenically cooled GaAs laser diode(5). The experiment was sufficiently defined to predict a rectangular retinal irradiation geometry. The retinal burns were in all instances circular in shape when viewed ophthalmoscopically, and were frequently oval in shape in retinal flat preparation and histopathological section (6).

MATERIALS AND METHODS.

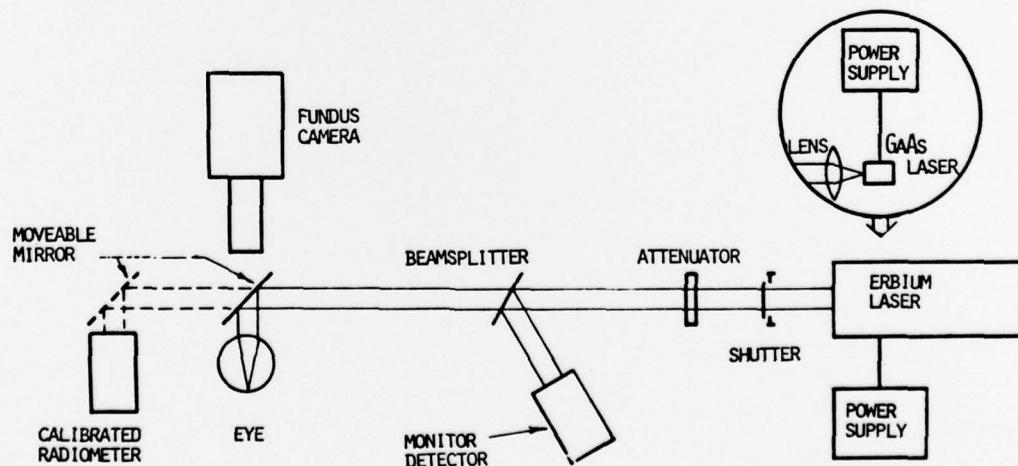


FIGURE 1: EXPERIMENTAL APPARATUS

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Experiments were conducted to provide sufficient data for further interpretation of the biomedical effects data base, utilizing lasers which approximated the MILES device in spectral and/or temporal emission characteristics.

The apparatus used in these experiments is shown in figure 1. A shutter controlled the exposure sequence and attenuating filters reduced the beam energy to the desired level. A beamsplitter directed a portion of the energy into a detector which recorded the dose of each exposure. This detector was calibrated by reference to a radiometer each day the system was used. A goniometer mount provided rotation of the animal about the pupil of the eye to be exposed, allowing precise positioning of the exposures on the retina. An accurately repositionable mirror, which directed the beam into the eye, was moved to permit fundus camera observation of the retinal exposure sites.

Each laser, as required, was positioned in the exposure system. The divergence of the beam at the eye exposure position was measured so that an accurate estimation of the size and geometry of the retinal image could be made.

The animals used in these experiments were rhesus monkeys (*Macaca Mulatta*) weighing between 2 and 5 kg. Preanesthetic medication consisted of a sedative dose of phencyclidine hydrochloride (0.25 mg/kg) intramuscular and atropine sulfate (0.2 mg) subcutaneously. Anesthesia was induced with sodium pentobarbital (approximately 5 mg/kg) via the saphenous vein. A pediatric intravenous injection set was placed into the saphenous vein to administer fluids and to facilitate additional anesthetic. The pupils were dilated and sutures of 3-0 silk were placed in the upper eyelid to facilitate manipulation. While the eyes were open during the experiment, physiologic saline was used to maintain good corneal transparency.

The animals were positioned in the exposure system and the fundus examined via the Zeiss fundus camera. Any abnormalities were noted. Thirty-six to forty eight exposures were placed in a square array utilizing suprathreshold marker burns to accurately locate the rows and columns for subsequent examination.

Detailed ophthalmoscopic examination of the exposure sites was conducted at one hour post exposure. The criteria for damage were the presence of a lesion visible via this examination.

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For most of the systems evaluated, a probit analysis was performed (7). The presence or absence of changes in appearance of the target area was noted for each irradiance studied. The ratio of observed responses to the total number of exposures at given doses was then plotted on logarithmic probability paper where the ordinate is probability (percentage observed) and the abscissa reflects the dose.

From the plot, the ED_{50} (effective dose required to produce an observable response 50 percent of the time) was obtained. Confidence intervals about the dose response curve were calculated. Because of the experimental design, the ED_{50} has greatest statistical significance and is often referred to as the "damage threshold."

ERBIUM: YLF EXPOSURE SERIES

This laser produced Q-switch pulses of 180-ns duration at a wavelength of 850 nm with a beam diameter of 1.6 mm.

Dose response data were obtained for two exposure conditions. Initial exposures used a laser beam divergence of 0.7 milliradian, producing a minimal retinal irradiation diameter. After an ED_{50} had been obtained for this condition, a +9 diopter lens was introduced into the beam to produce a 26.8 milliradian beam divergence resulting in a 400 μ m retinal irradiation diameter. The results of the 850-nm Erbium laser exposures are tabulated in Table I.

TABLE I

ED_{50} Dose for Q-Switch Erbium Laser Exposure - 850 nm

	ED_{50}
Minimum Retinal Irradiance Diameter	$12 \pm 3 \mu J$
400 μ Retinal Irradiance Diameter	$138 \pm 20 \mu J$

This experiment established the damage threshold for a single, short-duration pulse in the spectral region of the GaAs laser.

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NEODYMIUM: YAG - PULSE TRAIN EXPOSURE SERIES

The laser was a continuously pumped acousto-optic Q-switched Nd:YAG laser. The wavelength was 1064 nm. Within the pulse repetition frequency range of these experiments, the pulse duration was 180 ns. The laser was pulsed continuously at the desired frequency and an external shutter was used to pass the desired number of pulses. The laser beam at the eye was 2mm in diameter and collimated to produce a minimum retinal irradiation area. These data are summarized in Table II.

TABLE II
Laser Exposure Data Nd Laser Pulse Trains - 1064nm

PRF		Number of Pulses					
		1	2	3	6	74	
100Hz	ED ₅₀ (μJ)	128.9	75.1	89.8			1000
1000Hz	ED ₅₀ (μJ)		80.1	51	55	16.4	10.1
3000Hz	ED ₅₀ (μJ)		60.6	43.6	30.4		

These data show a high degree of additivity for two pulses, with the additivity being greater for shorter interpulse spacing. The degree of additivity lessens following the second pulse. If the data for 1000Hz is plotted on log paper as total pulse train energy vs total exposure duration, the slope of the resulting line is nearly identical to the slope of existing continuous wave (cw) neodymium laser ED₅₀ data. This is at variance with the guidance of TBMED 279 which assumes a different time dependency of the safe level for the two exposure conditions. This variance encouraged the investigators to perform a literature search for all existing pulse train exposure data. Examination of these data, for pulse durations from 10 ns to 1 ms and pulse repetition frequencies from 1Hz to 10,000Hz reveal a consistent relationship between pulse train data and equivalent continuous wave data. This relationship is not adequately modeled by the procedures of TBMED 279.

GALLIUM ALUMINUM ARSENIDE (GaAlAs) EXPOSURE SERIES.

The source of radiation for this experiment was a cw GaAlAs stripe geometry laser diode, selected to have a maximum laser output of not less than 20 mW. The wavelength of maximum emission, measured in this laboratory, was 883 nm. The spectral bandwidth was not measured, but is reported by the manufacturer to be 2.5 nm.

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The laser was driven with a stable 385 milliamp source. A 5.5-mm focal length lens collimated the laser emission. The beam divergence was 0.65 milliradian by 4.8 milliradian.

A horizontal row of 12 suprathreshold retinal exposures were made with the erbium laser to produce location markers. Three rows of GaAlAs laser exposures were located below the marker row.

All exposures were of 30-second duration. The ED_{50} , determined from 185 exposures in six eyes, was 230 millijoules. The lower and upper 95% confidence limits were 202 millijoules and 262 millijoules, respectively.

MILES PROTOTYPE EXPOSURE SERIES.

The laser source used in this experiment was a prototype gallium-arsenide laser training device having two modes of operation. In the pulse-repetition-frequency (PRF) mode, the output consisted of a continuous train of 100-ns, 905-nm pulses at a repetition rate of 1,600 Hz. In the pulse code mode, the interpulse spacing is not constant and the average repetition rate is 132 Hz. The pulse energy and duration are the same in both operating modes.

In each eye a total of forty-eight exposures were made in a grid pattern for exposure durations from 1 sec to 90 sec. The total intraocular energy was .212 erg/pulse for the 1 watt laser and 1.64 erg/pulse for the 10 watt laser.

Evaluation of the retinal sites was made by funduscopy observation, intravenous fluorescein angiography, retinal flat preparation, and/or epon imbedded serial sections for light microscopy (Trypan blue, azure II staining). These analyses were carried out for immediate, 1 hour and 24 hour intervals after laser exposure.

These ocular exposures did not produce the type of retinal opacity which is typically seen by funduscopy after laser irradiation of the retina. Exposures in the 30-second PRF sequences were characterized by the development of a pale gray clouding within 10 seconds after initiation of the exposure while the laser continued to irradiate the retinal site. At the end of the 30-second interval, the exposure site measured approximately 350-400 microns and was darkened at the periphery with central diffuse clouding (8).

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The incidence of observed retinal changes at various exposure levels is summarized in Table III.

TABLE III
Summary of MILES Prototype Laser Exposure Data

<u>Lasers</u>	<u>Mode</u>	<u>Exposure duration</u>	<u>TIE</u>	<u>Exposures/Changes</u>
watt	PRF	30 sec	1.0 mJ	100/67
		10 sec	0.34 mJ	25/18
		5 sec	0.17 mJ	7/5
		1 sec	0.034 mJ	10/0
1 watt	Pulse Code	30 sec	0.084 mJ	14/0
10 watt	PRF	30 sec	7.9 mJ	19/11
10 watt	Pulse Code	30 sec	.65 mJ	5/5

The subtle retinal changes were persistent (24 hrs after exposure). However, no fluorescein leakage or histological evidence of retinal alteration was confirmed in any of the exposure sites.

With the exception of the direct observation of retinal "clouding," none of the techniques (angiography, flat preparation, serial microscopy, and fundus photography) routinely used to determine the site or extent of the change demonstrated any retinal alteration.

DISCUSSION

Analysis of the results of these studies reveal a paradoxical situation. One result is a recommendation that the provisions of TBMED 279 be changed in a manner that allows the latest MILES device to be placed in Class 1 - safe laser (9). A second result is a body of biological data which indicates that retinal alterations are occurring at irradiance levels below those afforded by the MILES device. Note that there is an exact reversal of the condition which existed at the start of the study.

The ocular doses from the MILE prototype device which produced retinal "clouding" were below the existing TBMED 279 standard for pulse train irradiation. These doses approached those used in functional testing which produced measurable visual performance degradation.

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This subtle retinal clouding was a different end point response criteria than was used in the body of dose response data upon which the safety standards are based. Those data used the presence of a visible retinal opacity or lesion as a response criteria, as did the data reported here for the erbium laser, GaAlAs laser and repetitive pulsed Nd Laser. The clouding phenomenon does have correlates in other retinal response observations. The discrete lesion produced by the cw GaAlAs laser was surrounded by retinal clouding similar in appearance to that produced by the MILES prototype device.

Neodymium single pulse and multiple pulse exposures made at 2-3 X ED₅₀ produced a bright central whitened area of less than 100 μ m diameter which faded within ten seconds while the typical retinal opacity developed. At lower levels, approximating the ED₅₀ level, a reproducible change in the reflectivity from the retina was observed directly preceding the development of a retinal burn. At levels below the ED₅₀ the transient reflectivity change was the only effect noted.

Retinal effects for the erbium and GaAs lasers gave the impression that the changes are superficial to the retinal pigment epithelium for near "threshold" burn levels. If indeed changes are occurring superficial to the level of the pigment epithelium, then subtle exposures may produce damage to neural elements of the retina including the photoreceptors themselves without pigment epithelial change. Further, the accepted experimental ED₅₀ level, from which safe levels are determined, may be forced to be revised to account for other than retinal opacity levels.

COMPARISON OF DATA WITH STANDARD

Figure 2 presents the ED₅₀s for ocular exposure to the cw GaAlAs laser, the 120 KHz GaAs laser and the 180 nsec pulse duration 850 nm Erbium laser. Also presented are the ED₅₀s for ocular exposure to the cw neodymium laser and the pulsed neodymium laser. The neodymium laser data represented a consistent set derived in one laboratory with a common laser and observer. The neodymium data throughout were for minimal retinal irradiance diameter. The pulsed neodymium data and the pulsed erbium data are derived in one laboratory by a common observer using well behaved lasers in identical dose delivery systems. These data are therefore representative of the ratio of damage thresholds for the two wavelength regions.

The 850-950 nm data is inconsistent. The cw data does not lie on a common line and the separation between wavelength regions is

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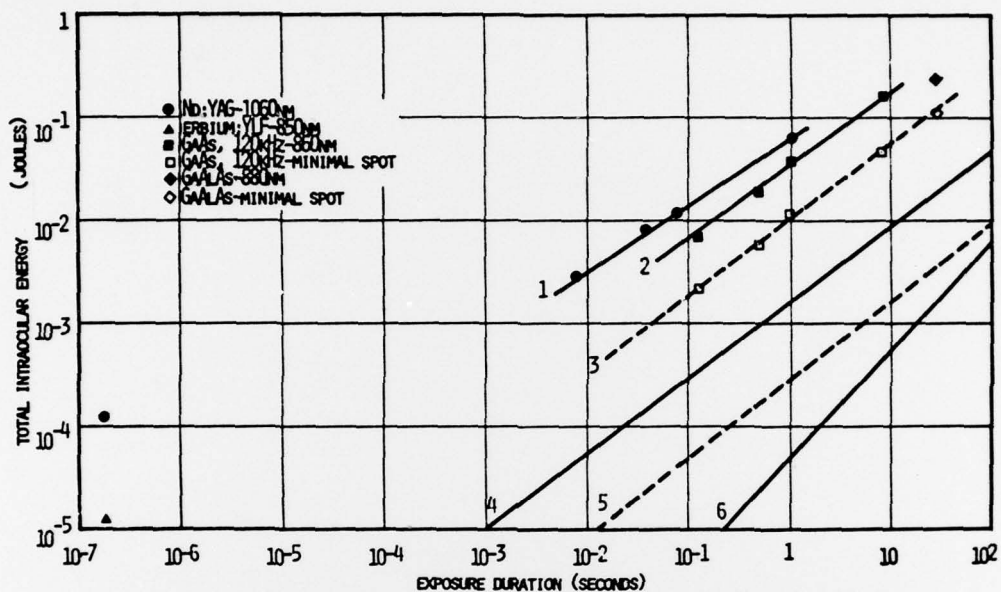


FIGURE 2: COMPARISON OF OCULAR DAMAGE THRESHOLDS
TO MAXIMUM PERMISSIBLE EXPOSURE LEVELS

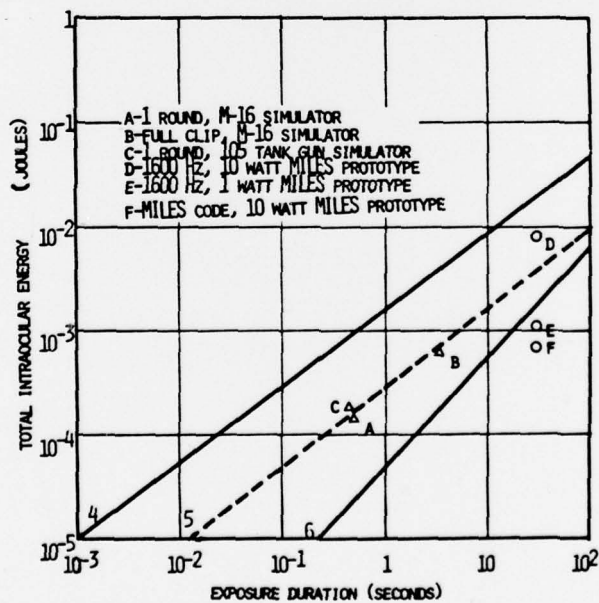


FIGURE 3: COMPARISON OF MILES DEVICE OUTPUT ENERGIES
TO MAXIMUM PERMISSIBLE EXPOSURE LEVELS

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not the same as that obtained with the pulsed lasers. The 120 KHz GaAs and cw GaAlAs data are not for minimal image diameter. Extrapolation is possible from these data to the estimated threshold for worst case conditions. Data collected for a variety of pulse durations, wavelengths, and retinal irradiance diameters show that, on the average, (10)

$$1) \quad \text{Log } E = k - \log D$$

where E is the retinal radiant exposure ED_{50} and D is the retinal irradiance diameter. From this equation can be derived the relationship:

$$2) \quad \frac{TIE_1}{TIE_2} = \sqrt{\frac{A_1}{A_2}}$$

where TIE is the total intraocular energy and A is irradiated area. The 120 KHz laser had a beam divergence of 11 milliradian by 0.2 milliradian. It is highly unlikely that eye would be able to produce the approximately 3 micron spot predicted from 0.2 milliradian divergence; a dimension of at least 20 microns is probable. The cw diode produced a beam divergence of 4.8 milliradian by 0.6 milliradian. The eye would again produce at least 20 micron spot from the 0.6 milliradian divergence. The 120 KHz diode irradiated a retinal spot of $165 \times 20 \mu\text{m}$ and the cw diode irradiated a retinal spot of $72 \times 20 \mu\text{m}$. From equation 2 the 120 KHz GaAs data must be reduced by a factor of 3.24 and the cw GaAlAs data reduced by a factor of 2.14. to present the worst case conditions (20 μ diameter spot). The estimated worst case line (line 3) is plotted on figure 2. This corrected data shows a consistent relationship to the neodymium data set.

Viewing multiple pulses is more hazardous than viewing a single pulse because of additivity of pulse effects. At question is the degree of additivity. Ocular damage thresholds were determined for exposure to pulse trains from a repetitively pulsed Nd laser. These measurements were designed to determine the additivity of the effectiveness of pulses as a function of pulse number and pulse separation. The consistent relationship between pulse train data and cw data led to the following formulation for computing the maximum permissible exposure to pulse trains.

$$3) \quad MPE^{RP}(T) = CF MPE(T)$$

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$MPE^{RP}(T)$ is the maximum permissible exposure expressed as total intraocular energy for the pulse train of duration T , $MPE(T)$ is the maximum permissible exposure for cw irradiation of duration T and CF is a correction factor which is dependent upon the pulse repetition frequency and the duration t of an individual pulse in the pulse train.

$$\begin{aligned} 4) \text{ for } t \text{ greater than } 2 \mu s \quad CF &= 3.5 PRFt^{-1} \\ \text{for } t \text{ less than } 2 \mu s \quad CF &= 1.8 \times 10^{-11} PRFt^{-1} \end{aligned}$$

This method has the advantage of applying the same margin of safety for pulse train exposures as is applied to cw exposures.

CF was derived by taking the ratio:

$$5) \quad CF = ED_{50}^{RP}(T) / ED_{50}(T)$$

$ED_{50}^{RP}(T)$ and $ED_{50}(T)$ are the damage threshold doses for pulse trains of total duration T and cw exposures of total duration T respectively.

Applying CF to the estimated worst case line for cw exposures yields a worst case (Figs 2, 3 line 4) for pulse train exposures. This line is shown for $PRF = 1,636 \text{ Hz}$, $t = 180 \text{ nsec}$, which are typical of MILES device parameters. The MPE for cw GaAs exposure (line 4) and the MPE^{RP} for pulsed GaAs exposure (line 5) derived by application of the CF for 1636 Hz , 180 nsec pulses are shown, as well as the MPE^{RP} obtained from TBMED 279 by application of C_p . (line 6) The emission energies of various MILES devices are shown for comparison. (Fig 3) In all cases, these energies are a factor of six below the projected ED_{50} levels and are approximately equal to the MPE^{RP} obtained by the CF method.

Another result obtained from the evaluation of pulse repetition data is:

$$6) \quad MPE^{RP}(T) = n^{3/4} Q MPE(t)$$

where n is the number of pulses in the pulse train, and $MPE(t)$ is the maximum permissible exposure for a single pulse. Q is a constant for any given pulse duration and wavelength, but its numerical value is not readily predictable. This relationship says that MPE^{RP} is essentially independent of PRF , but depends only on the number of pulses. Therefore, the results of the foregoing section are valid when applied to the average PRF of a non-uniformly spaced train of pulses.

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SUMMARY AND RECOMMENDATION

These studies indicate that there is a method and a justification for modifying the portions of TB MED 279 that govern the computation of the MPE for pulse trains, and a recommended procedure for so doing has been forwarded. These recommended changes allow a MILES system which is Class I in nature, as defined by a revised TB MED 279.

However, these studies further point out the fact that there is much we do not understand about the interaction between laser radiation and the visual system.

Little information is available on experimental data derived from fundoscopic evaluation of retinal exposures which describe changes other than the presence of retinal opacity. It may be that other wavelengths produce subtle visible persistent alteration which can be observed by ophthalmoscopy. The proposed changes in the standard do not take into account repeated exposures at intervals on the order of minutes to hours or the results of chronic viewing of low "safe" level laser source. Until these results are available both the developer and user must understand the limitations of the current recommendations. The current biomedical research data supports the recommendation that for the field use of this family of low power GaAs devices, a safe field use can be relatively assured. However, in the mode of operation where fixed optics and probability of continuous or repeated exposure exist, such as at the maintenance depot or other repair facility, manuals should specifically caution the intended user about viewing the laser source.

IN CONDUCTING THE RESEARCH DESCRIBED IN THIS PAPER, THE INVESTIGATORS ADHERED TO THE "GUIDE FOR LABORATORY ANIMAL FACILITIES AND CARE," AS PROMULGATED BY THE COMMITTEE ON THE GUIDE FOR LABORATORY ANIMAL FACILITIES AND CARE OF THE INSTITUTE OF LABORATORY ANIMAL RESOURCES, NATIONAL ACADEMY OF SCIENCES - NATIONAL RESEARCH COUNCIL.

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